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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,025	12/07/2001	Shun Luo	12951/60688	8990

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DEVINE, MILLIMET & BRANCH, P.A.
111 AMHERST STREET
BOX 719
MANCHESTER, NH 03105

EXAMINER

KENEDY, ANDREW A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,025

Applicant(s)

LUO, SHUN

Examiner

Andrew A. Kenedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Priority

Applicant's claim of the instant application as a Continuation-In-Part of copending application No. 09/943,937 filed on August 31, 2001, is acknowledged.

Applicant is accorded benefit to the filing date of August 31, 2001, of application No. 09/943,937 for claims 1-29.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath is defective because it does not identify the citizenship of the inventor.

Claim Rejections - 35 USC § 112

Claims 1-2, 4-10, 12-16, and 18-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Clippings of polyester fabrics are "samples", and would be encompassed by the language of the above claims. One of ordinary skill in the art would not know how to extract RNA from polyester fabric clippings, which are inorganic material, and the applicant's specification and claims do not teach how to extract RNA from these types of samples.

Claims 1-14, 20-21, 23-24, 26-27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preambles of independent claims 1, 9, and 29 state that the invention is a method and system, yet none of the claims include limitations drawn to a system. Rather, the claims only recite limitations drawn to methods. It is therefore unclear what applicant regards as the system.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim preamble states "A method and system for multiple parallel analysis of samples"; however, the applicant does not indicate in the body of the claim which component(s) constitute the samples. It is unclear whether the samples are the "array of known reagents", a constituent of the "array of known reagents", or the "at least one labeled cDNA." Applicant must clarify this.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Rava et al. (US 5874219 A). Rava et al. teaches a method and system for multiple parallel analysis of samples simultaneously, comprising: depositing an array of known reagents into as many wells of a multi-well microtiter plate platform as desired for a particular assay and immobilizing each said array thereon; depositing at least one labeled cDNA into at least one well of said multi-well microtiter plate platform; depositing at least one said labeled cDNA into as many wells having a said array therein as desired for a particular assay; allowing said each said labeled cDNA to hybridize to said array of known reagents in each said well; reading said microtiter plate platform after hybridization is completed; and using software, processing signals generated and read from said at least one label into a format useful for analysis (see at least col. 1 lines 34-44; col. 1, line 60 through col. 2, line 17; col. 2, lines 35-48; col. 3, lines 44-65; col. 7, lines 10-19; col. 7, line 64 through col. 8, line 6; and Fig. 3 and 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (US 6344316 B1) in view of Rava et al. (US 5874219 A).

Lockhart et al. teaches a method and system of analyzing samples by probe arrays, comprising: obtaining a number of samples to be analyzed (see at least col. 22, lines 10-22); extracting RNA from each said sample to be analyzed (see at least col. 22, lines 10-22); isolating mRNA from said RNA to use as a template for synthesizing DNA (see at least col. 22, lines 23-30; and col. 23, lines 2-3); synthesizing cDNA from each said mRNA of each said sample (see at least col. 21, lines 27-50); labeling each said cDNA with a label (see at least col. 24, lines 54-67); labeling each said cDNA with one of either a first or a second label (see at least col. 24, lines 54-67); and using software, processing signals generated and read from said at least one label into a format useful for analysis (see at least col. 61, lines 15-23); wherein each of two samples is labeled with a different label (see at least col. 24, lines 59-67); wherein each said sample is labeled with the same said label (see at least col. 24, lines 57-58; and col. 25, lines 64-67); wherein a universal or other control sample is used as an intra-array and inter-array normalization tool, and to define background and align image for reading (see at least col. 31, line 48 – col. 33, line 27; col. 45, lines 37-41; and col. 57, lines 7-32); wherein said reading is

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performed using a device capable of simultaneously reading two of the same type of signals (see at least col. 24, lines 59-67; and col. 47, lines 6-28); wherein said samples are chosen from the group consisting of: DNA, RNA, PNA, genes, portions of genes, polynucleotides, polypeptide biopolymers, fragments of DNA, fragments of RNA, short oligonucleotides, proteins and polypeptides (see at least col. 21, lines 45-50); wherein said label is chosen from the group consisting of: a fluorescent label, a radio label, a colorimetric label, or a reflective label (see at least col. 24, lines 37-55); wherein said reading is performed on a device capable of reading a signal chosen from the group consisting of: fluorescence, radioactivity, color intensity, and reflection changes (see at least col. 47, lines 6-46).

Lockhart et al. does not teach the above limitations in the context of multi-well microtiter plate platform. Additionally, Lockhart et al. does not teach the following limitations taught by Rava et al.

Rava et al. teaches a method and system for multiple parallel and simultaneous analysis of samples, comprising: depositing an array of known reagents into as many wells of a multi-well microtiter plate platform as desired for a particular assay and immobilizing each said array thereon (see at least claims 1-5; col. 1, lines 60-67; col. 3, line 44; col. 7, line 64 - col. 8, line 8; and Fig. 3 & 4); depositing at least one labeled cDNA into at least one well of said multi-well microtiter plate platform (see at least claims 1-5; col. 10, line 66 - col. 11, line 14; col. 3, line 54-65); depositing at least one said labeled cDNA into as many said wells having a said array therein as desired for a particular assay (see at least claims 1-5; and col. 2, lines 43-48); allowing each said labeled cDNA to hybridize to said array of known reagents in each said well (see at least claims 1-5); reading said microtiter plate platform after hybridization is completed

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(see at least claim 1; and col. 2, lines 26-30); wherein the number of samples to be assayed simultaneously is at least about 6 (see at least col. 4, lines 33-40; col. 7, line 65 – col. 8, line 8; and col. 9, lines 1-12); wherein two samples are deposited in each well of said microtiter plate platform (see at least col. 9, lines 11-12; col. 9, lines 1-8; and col. 2, lines 47-48); wherein said array of known reagents is deposited on the inner bottom surface of said well on an area in the maximum range of about 2.25mm x 2.25mm to about 36.0mm x 36.0mm, said area being dependent upon the number and size of wells formed in said microtiter plate platform and the density of the array deposited therein (col. 9, lines 28-30); wherein said inner bottom surface of each said well is glass (col. 9, lines 36-51).

It would have been obvious for one of ordinary skill in the art to combine the teachings of Rava et al. regarding biological chip array technology in a multi-well microtiter plate platform, with the biological array methods and systems taught by Lockhart et al., since Rava et al. teaches: "This invention provides automated methods for concurrently processing multiple biological chip assays. Currently available methods utilize each biological chip assay individually. The methods of this invention allow many tests to be set up and processed together. Because they allow much higher throughput of test samples, these methods greatly improve the efficiency of performing assays on biological chips" (col. 4, lines 33-40).

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is 703-305-4842 (after January 12, 2003, use telephone number 571-272-0574). The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4842.

A.A.K.
December 22, 2003

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
AC1631